AMENDMENTS TO THE DRAWINGS

Figs. 2, 5, 7C, and 11 have been amended with changes indicated on the accompanying Replacement Sheets. Replacement Sheets 1, 2, 3 and 6 are attached.

Attachments: Replacement Sheets

REMARKS

Claims 1-12 and 14-38 remain. Claims 1, 4, 9, 16, 24, 25, 28 and 35 are amended. No new matter has been added. Applicant respectfully requests favorable reconsideration and allowance in light of the remarks contained herein.

Oath/Declaration

The Office Action has objected to the oath or declaration as being defective due to the lack of application number, filing date, and because it does not identify the mailing address of each inventor. Examiner states that a new oath is required. Applicant submits however, that a new oath is not necessary pursuant to 37 C.F.R.§1.63(c). Accordingly, a Supplemental Application Data Sheet is attached to correct the lack of application number and filing date. No change has been made to the inventors' mailing addresses on the Supplemental Application Data Sheet, which are believed to be compliant with requirements under 37 CFR §1.76(b)(1).

Specification

The Office Action has objected to the title of the invention as not descriptive. While Applicant does not agree that the title is improper, Applicant has amended the title as shown above in order to advance prosecution. Therefore, Applicant requests that the objection to the title be withdrawn. Further, paragraphs [0020] and [0023] have been amended to fix typographical errors. Applicant submits that the present changes do not add new matter.

Drawings

The drawings are objected to as failing to comply with 37 C.F.R. § 1.84(p)(5) because they include reference characters 24, 56, 201, and 1002, not mentioned in the description. Applicant has amended Figure 2 to delete reference numeral 24. Applicant has amended Figure 5 to delete reference numeral 56. Applicant has amended Figure 7C to delete reference numeral 201. Applicant has amended Figure 11 to change the reference character 1002 to reference character 1102, which is mentioned in the description, at least in paragraph [0031] on page 6 of the specification. Applicant notes that this amendment to Figure 11 corrects a minor typographical error only. No new matter has been added by the

foregoing amendments. In view of the amendments to the Figures, Applicant respectfully requests that the objections to the drawings be withdrawn.

Rejections Under 35 U.S.C. § 112

Claims 18, 19, 30, and 31 are rejected under 35 U.S.C. § 112 first paragraph, as failing to comply with the enablement requirement. More specifically, the Office Action takes issue with the claims reciting a guide having a predefined closing angle, and a closing angle which is calibrated. The Office Action further states that the present disclosure makes no discussion of a predefined and/or calibrated closing angle, and as such a skilled artisan would not be reasonably apprised of how to achieve these limitations. These claims were not examined further on the merits of their patentability over the prior art.

Applicant respectfully submits that these features are clearly taught in the present specification. For example, paragraph [0025] discusses a closing angle with respect to the proximal end of the guide. The closing angle clearly creates the trajectory of the needle in the embodiment discussed in [0025]. Further the paragraph teaches that "this trajectory intersects the patient at the target depth (such as 1.5 cm) as indicated on the needle guide." Paragraph [0024] teaches that "the device guide is manufactured to control the placement of devices, such as catheter and needles, to multiple depths, by changing the angle of attack at which the needle (or catheter) is presented to the transducer."

Further, Figure 11 clearly illustrates devices having pre-defined and/or calibrated angles. While the figure is discussed in terms of depth of penetration, it is noted that the trajectory discussed in [0025] is with respect to the surface being probed. A change in the pre-defined target depth will cause a change in the pre-defined closing (*i.e.* attack) angle because the medical device must still be within the probe area when placed at the target depth. That is why, as taught in [0025], the closing angle is an angle formed with respect to the proximal end of the guide, and why, as taught in [0024], multiple depths are accomplished "by changing the angle of attack."

It is further noted that these claims are also self-enabling, such that one with skill in the art would understand how to make and use the claim containing the limitations, simply by reading the limitations. *See* MPEP 2164. For example, claim 30 recites "wherein said guide

has a predefined closing angle with respect to said proximal end of said probe and wherein said trajectory is predictable at least in part by said closing angle" and claim 31 recites "wherein said closing angle is calibrated to a depth below said surface of said object." Clearly, just by reading the claims one with skill in the art would know that the predefined closing angle of claim 30 is an angle with respect to the proximal end of the probe which contributes to the trajectory, and the closing angle may be calibrated to hit a depth below a surface of an object.

As a result, Applicant respectfully submits that the subject matter of claims 18, 19, 30 and 31 are clearly enabled in the specification. Therefore, Applicant requests that the rejection be withdrawn.

Claims 1-12 and 13-38 are rejected under 35 U.S.C. § 112 second paragraph, as being indefinite. More specifically, the Office Action takes issue with claim 1 as being incomplete for omitting essential elements "one or more medical device supports," such omission amounting to a gap between the elements. While Applicant does not agree with Examiner's interpretation, claim 1 has been amended for the sake of advancing prosecution. Applicant notes that the subject matter of this amendment was contained in the original claim as filed. Hence no new matter has been added.

The Office Action also takes issue with claim 4 which states that the bracket comprises at least one pivot point at the proximal end of said medical device support. Claim 4 has been amended to clarify the claim language. Accordingly, Applicant respectfully requests withdrawal of the present rejection. Applicant notes that the subject matter of this amendment was contained in the original claim as filed, and is illustrated in the figures of the present application. Hence no new matter has been added.

The Office Action takes issue with claim 9 which recites "said guide having a longitudinal seating area." Examiner suggests that the claim should read "said support having a longitudinal seating area." The claim has been amended accordingly. Applicant therefore requests that the present rejection be withdrawn. Applicant notes that the subject matter of this amendment merely corrects a typographical error. Accordingly, no new matter has been added.

In reference to claim 16, the Office Action states that the phrases "the longitudinal axis" lacks antecedent basis, and the phrase "positioned one of said medical device" is grammatically incorrect. Claim 16 has been amended for clarification purposes, and Applicant respectfully requests withdrawal of the present rejection. No new matter has been added.

The Office Action asserts that the phrase "the proximate end", "the longitudinal axis", and "said bracket" in claim 24 lack antecedent basis. Claim 24 has been amended to remedy Examiner's concerns. Thus, Applicant respectfully requests withdrawal of the present rejection. No new matter has been added.

On page 4 of the Office Action, Examiner recommends replacing the word "for" in the context of structural limitations of all pending claims with language such as "adapted to" or "configured to" in order to positively recite the limitations following such phrases. Examiner further states that limitations being cited "for" a purpose are interpreted as being nothing more than intended use restrictions that fail to place a positive structural limitation on the claims. Applicant does not believe this to be an accurate characterization of the law. *See* MPEP 2173.05 (g). Additionally, it is unclear as to what extent Examiner's statement has bearing on the claims. If Examiner is stating that patentable weight will not be given to a functional limitation, such a statement is improper. *See Id.* (stating that "[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used"). Regardless, amendments have been made to claims 24 and 25 as suggested by Examiner. Applicant notes that these amendments do not change the scope of the claims.

Rejections Under 35 U.S.C. § 102

Claims 1-12, 14-17, 20-29, and 32-38 are rejected under 35 U.S.C. § 102 as being anticipated by Pruter (U.S. Pat. 6,296,614, hereinafter "Pruter"). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference," *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Because the Pruter reference fails to teach each and every claim element in the present application, Applicant respectfully submits that the above rejections are improper.

Amended claim 1 recites "a plurality of medical device supports, one or more of said plurality of medical device supports being configured to create a different angle of attack than another of said plurality of medical device supports." This limitation is not taught by Pruter. It is noted that in Pruter, bracket 6 has edges 52 and 54 have different lengths which function to create and fix the angle of attack of any device placed within the support pieces. *See* Pruter col. 3 lines 36-41, figure 2. However, there is no teaching of differing supports which create different angles of attack. Accordingly, Applicant respectfully requests withdrawal of the present rejection.

Claim 9 recites "said latch fitted over said rod where said rod is seated in said seating area, said latch comprising a tapered wedge portion for positioning below a seated rod." This limitation does not appear to be addressed by the present Office Action. It is noted that nothing in Pruter can be characterized as a latch which fits over a rod and has a tapered wedge portion to be positioned below the rod. The Office Action states that, in Pruter, a latch with overhang 92 is placed over a needle. However, it is noted that nothing on that portion, or any other portion of Pruter, teaches a tapered wedge for positioning below a rod. Hence, the above limitation is not taught by Pruter and Applicant respectfully requests that the rejection be withdrawn.

Claim 16 has been amended to recite "a slidably coupled latch having a dimension keyed to the diameter of said medical device, wherein said slidably coupled latch comprises a wedge portion defining said dimension." Support for this amendment can be found throughout the specification (*see e.g.* figures 3-5, and 10). Applicant notes that Pruter does not teach a slidably coupled latch, nor does Pruter teach a latch having a wedge portion configured to create said dimension when coupled. As clearly shown in figure 4 of Pruter, the clamp 36 which secures a needle is pivoted and held shut by a spring force from item 28. This clamp is neither slidably coupled, nor does it latch. Further, there is no wedge portion on the clamp 36 which is configured to define the dimension of a medical device when clamped. As such, Applicant respectfully requests withdrawal of the present rejection.

Amended claim 24 recites "a slide configured to traverse said channel, said slide applying controlled clamping force on an accepted elongated medical device." This limitation is not addressed by the present Office Action. Further, it appears that Pruter does

not teach this limitation. In the event that the Examiner persists in this rejection, Applicant respectfully requests clarification as to how or where it is asserted that Pruter teaches the above limitation.

Applicant respectfully requests a full and fair examination of the claims and submits that it would be improper to cause the next office action to be made final. M.P.E.P. 706.07 states:

> Before final rejection is in order a clear issue should be developed between the examiner and applicant. To bring the prosecution to as speedy conclusion as possible and at the same time to deal justly by both the applicant and the public, the invention as disclosed and claimed should be thoroughly searched in the first action and the references fully applied....

Because Examiner did not consider the limitations of claim 24 in the present Office Action, in the event that the Examiner maintains the rejections, Applicant respectfully requests detailed grounds for such rejections and an opportunity to respond without the overshadowing of a final rejection.

Claim 28 has been amended to recite "said guide being selected from a plurality of guides which are adapted to form different angles of attack for said medical device." Support for this amendment can be found throughout the specification (*see e.g.* figure 11). As noted above with respect to claim 1, Pruter does not teach a plurality of guides which provide different angles of attack. Hence, Applicant requests that the rejection of claim 28 be withdrawn. No new matter has been added.

Claim 35 is currently amended and recites "releasably attaching a needle to said attached needle guide by sliding a clamping mechanism within said selected one of said needle guides so that the longitudinal axis of said needle lies along a longitudinal axis of said selected one of said needle guides, said needle having said particular gauge." Support for this amendment can be found throughout the specification (*see e.g.* figures 3-5, and 10). Nothing in Pruter teaches releasably attaching a needle to a guide by *sliding* a clamping mechanism within the guide (*see* arguments above for claim 16). As a result, Applicant requests that the rejection be withdrawn.

Claims 2-8, 10-12, 14-15, 17, 20-23, 25-27, 29, 32-34, and 36-38 depend either directly or indirectly from independent claims 1, 9, 16, 24, 28, or 35, and thus inherit each and every limitation of their corresponding independent claim. As a result, claims 2-8, 10-12, 14-15, 17, 20-23, 25-27, 29, 32-34, and 36-38 are allowable for at least the reasons set forth above. Further, dependent claims 2-8, 10-12, 14-15, 17, 20-23, 25-27, 29, 32-34, and 36-38 contain aspects that are patentable in their own right.

Conclusion

In view of the above, Applicant believes the pending application is in condition for allowance and respectfully requests favorable reconsideration.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2380, under Order No. 65744/P016US/10316060 from which the undersigned is authorized to draw.

Dated: August 14, 2008

Respectfully submitted,

By _____

R. Ross Viguet
Registration No.: 42,203
FULBRIGHT & JAWORSKI L.L.P.
2200 Ross Avenue, Suite 2800
Dallas, Texas 75201-2784
(214) 855-8185
(214) 855-8200 (Fax)
Attorney for Applicant

Attachments: Supplemental Application Data Sheet
Replacement Sheets